K121479

Section 5: 510(k) Summary

SEP 13 2012

Submitted by: **InnerOptic Technology, Inc**

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Date Summary Prepared: **05/17/2012**

Proprietary Name: AIM

Common Name: Ultrasonic pulsed echo imaging system

Regulatory Class: Class II per 21 CFR 892.1560

Product Codes: IYO: system, imaging, pulsed echo, ultrasonic
OEW: tracking, soft tissue, intraoperative

Device Description: AIM is an accessory to ultrasound systems that provides guidance for the placement of needles or needle-like rigid objects, such as biopsy needles and ablation probes. The system enables a physician to accurately place a needle into a target anatomical structure by overlaying the image of the needle and its predicted future path on the ultrasound image of the internal organs in real time on a stereo monitor, for a "3D" effect (cf. IMAX 3D theaters).

AIM consists of four (4) principal components:

(1) an electromagnetic position tracking system;
(2) tracking sensors and mounts for the ultrasound transducer and the needle;
(3) custom guidance software installed on a computer; and
(4) a stereoscopic monitor with passive glasses for viewing the monitor.

Intended Use: AIM is indicated for enhancing the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an

aspiration needle, or ablation needle, and for predicting its future path on a stereoscopic computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualizing such procedures.

Technological characteristics, comparison to predicate device: The technological characteristics and indications for use of AIM are the same or similar to those found in the predicate device. AIM is substantially equivalent to InnerOptic's InVision System cleared in K083728.

The AIM device labeling contains instructions for use, including indications for use, cautions, contraindications, warnings and planning guidance. This information assures safe and effective use of this device.

Discussion of performance testing: Testing was conducted to evaluate the performance characteristics of AIM. A novice user made placement attempts in tumor mimics within agar phantom gels, both with and without AIM's guidance, at two different angles of approach – 0 degrees ("in plane"), and 90 degrees ("out of plane"). The novice's success rate with AIM's guidance was 92%, and without it was 8%.The results of these studies demonstrate that AIM is capable of safely and accurately performing the stated intended use. The results also show similar effectiveness to AIM's predicate device, the InVision System (K083728).

Conclusion: AIM is equivalent to the predicate device in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Ms. Caroline Green
Regulatory Manager
InnerOptic Technology, Inc.
106-A N. Churton Street
HILLSBOROUGH NC 27278

Re: K121479
Trade/Device Name: AIM
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and OEW
Dated: August 15, 2012
Received: August 20, 2012

Dear Ms. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: _____

Device Name: **AIM**

Indications for Use:

AIM is indicated for enhancing the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a stereoscopic computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualizing such procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
OIVD

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